K031600

AUG 13 2003

MICOR, INC
CONFIDENTIAL

Summary of Safety and Effectiveness
21 CFR 807.92(a)(6)

Date of preparation of Summary: May 21, 2003

MICOR Contact:

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Device Name:

1. Common name - Conduction Catheter
2. Trade name - not applicable at this time
3. Classification Name:
   a. Device name: Conduction catheter
   b. Speciality: Anesthesiology
   c. Product code: FRN
   d. Device class: 2
   e. Regulation: 21 CFR 880.5725

Predicate Devices:

1. K991879 MICOR EpiFlex Epidural Catheter
2. K001717 MICOR Epidural Conduction Catheter
3. K003966 MICOR Conduction Catheter
4. K003611 Pain Care Multi-Port Catheter

Product Description/Function:

1. Description:
   a. The subject device is available as a closed end with multiple holes, fenestrated area, located radially along the lateral surface at the distal end of the device.
   b. The subject device is radiopaque and is available in 19g and 20g sizes.
2. Function:
   a. The fenestrated area provides the distribution of anesthetic over the surgical wound sites.
   b. The stainless steel coil increases the flexibility and kink resistance of the catheter.

Technological Characteristics:

1. Technological Characteristics of the subject device are substantially equivalent to the predicate devices K991879 and K003966 manufactured by MICOR, INC.

Materials:

1. The polyamide co-polymer, stainless steel coil and black ink used in the subject device is substantially equivelent to the materials used in the predicate devices K991879 and K003966 manufactured by MICOR, INC.

K031600

Intended Use:

1. The intended use of the subject device is for the administration of local anesthetics into intra-operative sites for post-operative pain management and for regional anesthesia outside of the epidural space. Routes of administration may be intra-operative, subcutaneous or percutaneous.
2. The intended use of the subject device is equivalent to the predicates K003966 and K003611

Safety and Effectiveness:

1. No new issues of safety and effectiveness are raised by the design of the subject device.
2. The subject device is substantially equivalent in its performance to predicate K003966 and in its intended use to predicates K003966 and K003611

Conclusion:

1. The design, performance, materials, intended use and safety and effectiveness of the subject device is substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2003

Ms. Susan Forgrave
Quality Assurance & Regulatory Manager
Micor Incorporated
2855 Oxford Boulevard
Allison Park, Pennsylvania 15101

Re: K031600
Trade/Device Name: Conduction Catheter
Regulation Number: 880. 5725
Regulation Name: Accessary to Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: May 20, 2003
Received: June 3, 2003

Dear Ms. Forgrave:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MICOR, INC
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Indications For Use Statement
21 CFR 807.92(a)(5)

K031600
510(k) number(if known)

Device name: Conduction Catheter

Indications for use:

The Conduction Catheter is intended for administration of local anesthetics into intra-operative sites for post operative pain management and for regional anesthesia outside of the epidural space.
Routes of administration may be intra-operative, subcutaneous or percutaneous.
The Conduction Catheter is not intended for intravenous or intra-muscular use.

Please do not write below this line – continue on another page if needed

Concurrence of CDRH Office, Office of Device Evaluation (ODE)

Prescription use ✓ OR Over-the-Counter _____

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031600